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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,874	04/10/2001	Joel S. Douglas	018176-381	1056

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EXAMINER

SMITH, ZANDRA V

ART UNIT	PAPER NUMBER
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2877

DATE MAILED: 01/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/828,874

Applicant(s)

DOUGLAS ET AL.

Examiner

Zandra V. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Preliminary Amendment*

The preliminary amendments filed April 10, 2001 have been entered.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)*.

As to **claims 8 and 10**, Grant discloses a test strip holding and reading meter, comprising:

an electronic printed circuit board having alignment fixturing:

an optics system for alignment with the removable test strip, the optics system

comprising an emitter, prisms, and a detector and mounted on the printed circuit board (col. 9, lines 32-50);

a housing (col. 7, lines 10-15);

an optics block holder mounted in the printed circuit board for aligning the test strip and positioning the optics system to focus light (col. 9, lines 32-50); and

a processor controlling the assay system in accordance with calibration information specific to a reagent associated with the test strip (col. 18, lines 45-58), the processor also

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controlling the assay system such that a predetermined number of test strips are assayed (col. 17, lines 1-18).

Grant differs from the claimed invention in that a lens is not provided in the optical system, however the examiner takes Official Notice to the use of a lens as being obvious to one having ordinary skill in the art at the time of invention as a means to properly focus the light onto the sample and detector.

Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)* in view of *DeSimone et al. (4,833,088)*.

As to **claims 9 and 11**, Grant discloses everything claimed, as applied above, with the exception of a removable calibration chip, however to do so is well known as taught by DeSimone. In the same field of endeavor DeSimone discloses a reagent strip handling mechanism that includes a calibration chip mounted on the reagent strip and removable for cleaning (col. 11, lines 12-21). It would have been obvious to one having ordinary skill in the art at the time of invention to include a removable calibration chip to allow for cleaning of the chip.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)* in view of *McAleer et al. (5,989,917)*.

As to **claim 12**, Grant discloses a test strip holding and reading meter, comprising:  
an electronic printed circuit board having alignment fixturing;  
an optics system for alignment with the removable test strip, the optics system comprising an emitter, prisms, and a detector and mounted on the printed circuit board (col. 9, lines 32-50);  
a housing (col.7, lines 10-15); and

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an optics block holder mounted in the printed circuit board for aligning the test strip and positioning the optics system to focus light (col. 9, lines 32-50).

Grant differs from the claimed invention in that a lens is not provided in the optical system, however the examiner takes Official Notice to the use of a lens as being obvious to one having ordinary skill in the art at the time of invention as a means to properly focus the light onto the sample and detector.

Additionally, Grant fails to specifically provide the processor controlling the assay system such that the test strips are assays up to a predetermined expiration date, however to do so is well known as taught by McAleer. In the same field of endeavor McAleer discloses a glucose monitor and test strip container which includes a microprocessor controlling the system such that the test strips are assays up to a predetermined expiration date (col. 4, lines 22-35). It would have been obvious to one having ordinary skill in the art at the time of invention to include a processor controlling the assay system such that the test strips are assays up to a predetermined expiration date to avoid false readings.

As to **claim 13**, the system of Grant and McAleer discloses everything claimed, as applied above, in addition the predetermined expiration date corresponds to a set of one or more test strips (McAleer, col. 4, lines 22-35).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,285,454 in view of Grant et al. (EP 573598).

As to **claims 8 and 10**, '454 discloses an electronic printed circuit board, optics system, housing, optics block holder, and processor in claim 1. '454 differs in that the particular functioning of the processor is not specifically provided, however to do so is well known as taught by Grant. In the same field of endeavor Grant discloses a test strip holding and reading meter which includes a processor controlling the assay system in accordance with calibration information specific to a reagent associated with the test strip (col. 18, lines 45-58), the processor also controlling the assay system such that a predetermined number of test strips are assayed (col. 17, lines 1-18). It would have been obvious to one having ordinary skill in the art at the time of invention to include a processor performing those function to ensure that the proper reagent is identified.

Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,285,454 in view of McAleer et al. (5,989,917).

As to **claim 12**, 454 discloses an electronic printed circuit board, optics system, housing, optics block holder, and processor in claim 1. '454 differs in that the particular functioning of

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the processor is not specifically provided, however to do so is well known as taught by McAleer. In the same field of endeavor McAleer discloses a glucose monitor and test strip that includes a microprocessor controlling the system such that the test strips are assays up to a predetermined expiration date (col. 4, lines 22-35). It would have been obvious to one having ordinary skill in the art at the time of invention to include a processor controlling the assay system such that the test strips are assays up to a predetermined expiration date to avoid false readings.

### *Fax/Telephone Numbers*

**If the applicant wishes to send a Fax dealing with either a proposed amendment or for discussion for a phone interview, then the Fax should:**

**\_\_\_\_\_ 1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the Fax cover sheet; and**

**2) Should be unsigned by the attorney or agent.**

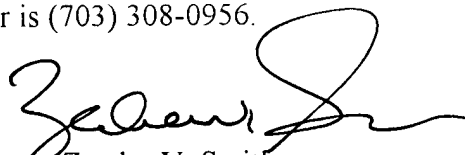
This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

***Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is:***

**(703) 308-7722**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Examiner* Zandra V. Smith whose telephone number is (703) 305-7776, and who is available Monday - Friday 6:30 a.m. - 4:00 p.m..

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0956.

  
Zandra V. Smith  
Patent Examiner  
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